PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the application of	Examiner: M. Han
Lee et al.	Group Art Unit: 3763
Serial No.: 09/451,902	Docket No.: ACSC 60541
Filed: December 1, 1999	DECLARATION BY JEONG S. LEE UNDER 37 C.F.R. §1.132
For: MEDICAL DEVICE BALLOON	

Commissioner for Patents
Washington, D.C. 20231

Dear Sir:

I, Jeong S. Lee, depose and say that

1. I am one of the joint inventors in the above-referenced application.

2. Ten samples of balloon tubing, formed of PEBAX (polyether block amide) 70D, having an inner diameter of about 0.0195 inches and an outer diameter of about 0.0355 inches, were used to prepare ten catheter balloons. The balloons had an outer diameter of about 3.0 mm, a length of about 20 mm, and a blow up ratio of about 6 (balloon outer diameter divided by balloon tubing inner diameter). The average compliance and rupture pressure data for the balloons is shown in Exhibit A.

3. The balloons had an average rupture pressure of about 21 atm (310 psi), with a standard deviation of about 1 atm (15 psi). The balloons had an average radial compliance of about 0.041 mm/atm from a nominal outer diameter of about 3.05 mm at about 6 atm to an outer diameter of about 3.253 mm at about 11 atm.

4. Comparing the average compliance of the balloons formed of 100% PEBAX 70D set forth in Exhibit A (i.e., 0.041 mm/atm), to the average compliance of the balloons of Example

1, at pages 14-16 of Applicants' specification, formed of a blend of 40% PEBAX 70D and 60% PEBAX 63D (i.e., 0.034 mm/atm from 8 to 15 atm), the balloons formed of 100% PEBAX 70D had an average compliance which was greater than the average compliance of the balloons formed of 40% PEBAX 70D/60% PEBAX 63D. The average compliance of the balloons of Example 1 formed of the 40% PEBAX 70D/60% PEBAX 63D blend is therefore not substantially greater than (and is in fact less than) the compliance of the balloons formed of 100% PEBAX 70D set forth in Exhibit A . The difference between the average compliance of the balloons formed of 100% PEBAX 70D set forth in Exhibit A and the average compliance of the balloons of Example 1 formed of the 40% PEBAX 70D/60% PEBAX 63D blend appears to be within the standard deviation thereof.

5. Comparing the average rupture pressure of the balloons formed of 100% PEBAX 70D set forth in Exhibit A (i.e., about 21 atm), to the average rupture pressure of the balloons of Example 1 on pages 14-16 of Applicants' specification formed of a blend of 40% PEBAX 70D and 60% PEBAX 63D (i.e., about 20 atm), the balloons formed of the 40% PEBAX 70D/60% PEBAX 63D blend had an average rupture pressure which was not more than about 5% less than the average rupture pressure of the balloons formed of 100% PEBAX 70D. The average rupture pressure of the balloons of Example 1 formed of the 40% PEBAX 70D/60% PEBAX 63D blend is therefore not substantially less than the average rupture pressure of the balloons formed of 100% PEBAX 70D set forth in Exhibit A . The difference between the average rupture pressure of the balloons formed of 100% PEBAX 70D set forth in Exhibit A and the average rupture pressure of the balloons of Example 1 formed of the 40% PEBAX 70D/60% PEBAX 63D blend appears to be within the standard deviation thereof.

6. Balloons formed of the 40% PEBAX 70D/60% PEBAX 63D blend and formed using optimized blow up ratios and heating conditions (e.g., temperature during expansion of the balloon tubing, and heat treatment temperatures after expansion of the balloon tubing) have compliance and rupture pressures which are equal to, or at least not substantially different from, balloons formed of 100% PEBAX 70D and formed using optimized blow up ratios and heating conditions, as discussed in Applicants' specification at page 4, lines 12-18 and page 12, lines 8-13, and as indicated in the above comparison of the balloons of Exhibit A and Example 1.

7. As discussed in Applicants' specification at page 5, lines 2-9, because PEBAX 63D has a lower Shore D durometer hardness than PEBAX 70D and is thus softer and weaker (as indicated by, for example, a lower ultimate tensile strength at break) than PEBAX 70D, blending PEBAX 63D (especially up to 60% by weight) into PEBAX 70D would be expected produce a balloon with a substantially higher compliance than a balloon formed solely of PEBAX 70D, and would be expected to produce a balloon with a lower rupture pressure than a balloon formed solely of PEBAX 70D. This is evident in Table 3 in Applicants' specification at page 19, where balloons formed of 100% PEBAX 63D had a higher average compliance and a lower average rupture pressure.

8. Example 4 at page 22 of Applicants' specification sets forth a comparison of flexural modulus measurements made on specimens of extruded tubing. The average flexural modulus, using a three point bend test, from a sample of 6 specimens was 15.7 gram/mm for the PEBAX 70D 100% formulation, and 11.5 gram/mm for the PEBAX 70D/63D 40%/60% formulation, indicating that the addition of lower Shore D durometer material (i.e., PEBAX 63D) to PEBAX 70D did increase the flexibility of the extruded tubing.

9. Selecting the claimed blend compositions and forming the balloon with optimized conditions such as blow up ratios and heating conditions during balloon blowing provided the balloons having the desired high softness (low flexural modulus) in combination with a rupture pressure and compliance substantially similar to the rupture pressure and compliance of balloons formed of 100% PEBAX 70D. Other PEBAX blend ratios were used to prepare balloons. However, not all PEBAX blend ratios provided the desired highest softness (lowest flexural modulus) in combination with a desirable high average rupture pressure and optimum compliance substantially similar to the rupture pressure and compliance of balloons formed of 100% PEBAX 70D. For example, the balloon tubing of Example 4 of Applicants' specification, formed of a blend of 80% PEBAX 70D/20% PEBAX 63D had an average flexural modulus of about 14.4 gram/mm, which is about 25% greater than the flexural modulus of the balloon tubing in Example 4 formed of the 40% PEBAX 70D/60% PEBAX 63D blend. This is expected to translate to poorer performance of a catheter having a balloon formed of 80% PEBAX 70D/20% PEBAX 63D compared to a catheter having a balloon formed of 40% PEBAX 70D/60% PEBAX 63D when assembled on the same catheter chassis.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the above identified application or any patent issued thereon.

Date: Jan. 28, 2003 Tony Lee

EXHIBIT A

Tubing/Balloon

Tubing: Pebax 70D
ID/OD: .0195"/.0355"
Bln Size: 3.0mm

COMPLIANCE DATA

Pressure		Sample No. (OD in mm)										AVG OD	Regress.
PSI	ATM	1	2	3	4	5	6	7	8	9	10	(mm)	Fit
30	2	2.716	2.719	2.725	2.782	2.706	2.695	2.744	2.700	2.707	2.707	2.720	2.834
45	3	2.795	2.872	2.809	2.871	2.812	2.785	2.828	2.802	2.803	2.802	2.818	2.877
60	4	2.887	2.897	2.896	2.954	2.878	2.880	*3.266	2.889	2.895	2.896	2.897	2.920
75	5	2.973	2.974	2.986	3.009	*3.628	2.963	2.984	2.970	2.978	2.975	2.979	2.963
90	6	3.038	*5.925	3.031	3.059	3.034	3.036	3.127	3.037	3.048	3.042	3.050	3.006
105	7	3.095	3.098	3.082	3.111	3.090	*6.495	3.104	3.092	3.105	3.099	3.097	3.049
120	8	3.163	*3.268	3.132	3.158	3.138	3.143	3.146	3.141	3.148	*3.884	3.146	3.092
135	9	3.187	3.186	3.174	3.191	3.182	3.186	3.183	3.180	3.188	3.188	3.185	3.135
150	10	*3.446	3.215	3.213	3.222	3.219	3.217	3.216	*3.625	3.222	3.224	3.219	3.178
165	11	3.262	3.250	3.250	3.250	3.250	3.249	3.252	3.251	3.254	3.261	3.253	3.221
180	12	3.298	3.285	3.283	3.280	3.279	3.285	3.284	3.285	3.284	*3.499	3.285	3.264
195	13	3.332	*12.114	3.317	3.312	3.315	3.312	3.316	3.318	3.319	3.327	3.319	3.307
210	14	3.367	3.349	3.349	3.342	3.344	3.342	3.350	3.352	3.351	3.358	3.350	3.350
225	15	3.404	3.381	3.379	3.377	3.383	3.375	3.384	3.387	3.384	3.392	3.385	3.393
240	16	3.440	3.417	3.415	3.414	3.419	3.408	3.422	3.425	3.423	3.426	3.421	3.436
255	17	3.483	3.453	3.451	*3.786	3.459	3.443	3.458	3.460	3.458	3.464	3.459	3.479
270	18	3.517	3.496	3.493	3.485	3.497	3.483	3.499	3.500	3.496	3.507	3.497	3.522
285	19	3.555	3.536	3.530	*4.023	3.539	3.521	3.539	3.543	3.537	3.547	3.539	3.565
300	20	3.601	3.585	*4.842	3.573	3.582		3.585	3.592		3.593	3.587	3.608
315	21		3.644	3.629	3.623	3.639					3.644	3.636	3.651
330	22				*3.926	3.700						3.700	3.694

MAX PRESS. (psi)	311	317	330	330	330	285	314	303	289	315	312.40

COMPLIANCE (mm/atm)											AVG
2 - RUPT	0452	.0429	.0431	.0398	.0439	.0445	.0413	.0444	.0440	.0442	.0430